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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	7

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on 6/24/96

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 13-18 is/are pending in the application.

Of the above, claim(s) 17 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 13-16 & 18 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

Claim 15 has been cancelled. Claims 13 has been amended. Claims 13-14 and 16-18 are pending.

Applicants' arguments filed 2/28/97 have been considered and found not persuasive.

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Applicants should revise the abstract to reflect the subject matter now claimed. In addition, the length of the abstract should be reduced to less than one page.

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. §112, first paragraph, for failing to provide an enabling disclosure.

Applicants have alleged that "[w]ith A3.5, Ala-boroPro suppressses HIV below detectable levels in a manner similar to the anti-HIV effect of AST at 1 μM". Applicants have also stated (p. 20) that Ala-boroPro and Pro-boroPro inhibit DP-IV *in vitro*. Applicants are extrapolating, however, to various other

substrates they will recognize; the effects of varying the N-terminal amino acid are unknown. In particular, peptides bearing an Asp, Glu, Arg or Lys residue at the N-terminus are likely to be inactive. Applicants have tested only two amino acids in this position, and they are both hydrophobic. If the second amino acid (from the "C-terminus") is at all important to enzyme recognition, loss of activity is likely with these embodiments.

Claims 13-14, 16 and 18 are rejected under 35 U.S.C. §112, first paragraph, for the reasons set forth in the objection to the specification.

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Claims 13-14, 16 and 18 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Given that "m" can only be zero, the claims would be clearer if the structure in brackets which is taken "m" times were eliminated, and reference to amino acid "A" also eliminated. Also, the phrase "A' and C" (4th line from last) should be eliminated. This issue also applies to claim 14, where reference to amino acid "A" has become superfluous. Thus, claim 14 might recite the following:

*

Claims 13-14, 16 and 18 are rejected under 35 U.S.C. §102(e) as being anticipated by Bachovchin (USP 4,935,493).

As indicated previously, Bachovchin teaches the following dipeptide:

Pro-boroPro.

(See the formula in col 1, line 50+; also "X" can be prolyl as stated in col 2, line 47).

Applicants have traversed by arguing that the peptides produced by the Bachovchin process are racemic, whereas the instant claims are drawn to L-isomers only, and that a stereochemical purification step is required in order to obtain chirally pure product. The examiner will stipulate for the sake of argument that such a purification step is required. The examiner will further stipulate that it is entirely possible that a claim drawn to a specific method of preparation of the claimed compounds, including a stereochemical purification step that had not been previously been applied to peptides, could be novel in view of the prior art. But the claims are drawn to compounds, not to a method of purification. The reference discloses at least one of the claimed compounds. In peptide biochemistry, amino acids are generally considered to be of the L-configuration unless indicated otherwise. L-amino acids are those that are

protease activity), such substitutions often lead to loss of activity. The peptide biochemist of ordinary skill, considering the reference, would conclude that L-amino acids are included, if not preferred. But even those who reject this argument would have to contend with the fact that there are only two possibilities, "L" and "D", of which the former is by far the most commonly employed.

The conveyance of "L" stereoisomers by a reference which teaches amino acids, but is silent as to the stereochemical disposition of the α-carbon, is at the very least, compellingly obvious; with respect to the instant situation, nevertheless, the examiner adheres to his earlier assertion of anticipation.

The rejection is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SUPERVISORY